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| 10/569,784 | 02/24/2006 | Roland Jermann | 21901US(C038435/0196414) | 6549 |

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| EXAMINER | |
|---|---|
| RAO, SAVITHA M | |
| ART UNIT | PAPER NUMBER |
| 4131 | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/569,784 | JERMANN ET AL. | |
| | Examiner | Art Unit | |
| | SAVITHA RAO | 4131 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/24/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

**Claims 1-19 are Pending**

### *Information Disclosure Statement*

Receipt is acknowledged of the Information Disclosure Statement filed 02/24/2006. The Examiner has considered the reference cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

Instant claims 1-2 recite the composition for "lightening the skin/smoothening skin color irregularities and/or treating senile lentigos" which is intended use and carries no patentable weight.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 9-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16-17 are vague and indefinite in that the metes and bounds of the claims are unclear. Claim 16 is indefinite in that it is written as a dependent claim without providing claim on which it depends, therefore the limitations of claim 16 cannot be accurately examined. Claim 17 is also indefinite since it is dependent on claim 16.

Claims 1-3, 9-16, 18 are rejected as it recites the term "derivative" either as biotin derivative or Vitamin C derivative. The 10th edition of the Merriam-Webster's Collegiate Dictionary (Merriam-Webster Incorporated: Springfield, Massachusetts, 1993, pp 311) defines "derivative" as, "a chemical substance related structurally to another substance and theoretically derivable from it." For example, carbon dioxide could theoretically be derived from the combustion of Biotin or Vitamin C. Therefore, the definition of derivative in the Merriam-Webster Collegiate Dictionary does not shed light on what Applicants' intended for the meaning of a Biotin and Vitamin C derivative.

***Claim Rejections - 35 USC § 102(b)***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-2, 4-5, 7, 9-13 and 19 are rejected under 35 U.S.C. 102 (b) as being anticipated by Raschke et. al. (US 6436414).

   Raschke discloses active ingredient combinations of biotin and/or biotin derivatives and cyclodextrins in combination with a suitable antioxidant and method for cosmetic preparations. Specifically Raschke discloses:

   a. A composition comprising of Biotin ester (Column 21, lines 17-18 to column 22 lines 11-13, Claim 2), a preferred derivative of biotin ester (Column 4 lines 16-23) and method of preparation and examples of topical compositions (Column 17,

lines 54-66; Column 18 line 1 to Column 20 line 54) as specified in instant claims 1, 4, 5, and 7.

b. Total amount of biotin and/or biotin derivatives in the finished cosmetic or dermatological preparations (Column 8, lines 9-13) as specified in instant claims 9, 10.

c. Compositions with an additional content of antioxidants which includes Vitamin -C and derivatives (Column 9, lines 36-41; Column 10, lines 2-4) as specified in instant claims 2, 11 and 19.

d. Total amount of antioxidants in the cosmetic preparations (Column 10, lines 20-24) as specified in the instant claims 12 and 13

2. Claims 1, 3, 5, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Della Valle et.al. (US 5550249).

Della Valle discloses:

a. A pharmaceutical compositions, containing at least one of the biotin salts in combination with suitable excipients and/or diluents (Column 3, lines 37-40; Column 6 , lines 8-45) as specified in instant claims 1, 3 and 8.

b. A pharmaceutical composition containing biotin salt in combination with a suitable excipient for oral administration (Column 6, lines 8-45; Column 8, lines 4-6, claim 8) as specified in instant claim 6.

c. A pharmaceutical composition containing biotin salt in combination with a suitable excipient for topical administration (Column 8, lines 1-3) as specified in instant claim 5

3. Claims 2, 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Lanzendorfer et. al. (US 5952373).

Lazendorfer discloses:

a. Method for the treatment of hyperactive skin predisposed to dermatitis with an effective amount of a composition comprising of flavanoids with an antioxidant such as Vitamin C and derivatives (Column 9 lines 10-12) and an active compound which regulate energy metaboism such as D-biotin and derivatives (Column 9, lines 52-54, Example 25 listed below) as specified in instant claims 2, 11, 12 and 13.

EXAMPLE 25

| Water-in-oil emulsion (sunscreen milk) | % by weight |
|---|---|
| $FADH_2$ | 0.09 |
| Glucose 1,6-phosphate | 1.23 |
| D-Biotin | 0.04 |
| D-Camosine | 1.0 |
| Vitamin C dipalmitate | 2.0 |
| Vitamin E acetate | 3.0 |
| Phytic acid | 1.70 |
| Uronic acid | 1.30 |
| L-Cysteine | 1.57 |
| Dithiopropyl gallate | 4.00 |
| 2-Ethylhexyl, 4-methoxycinnamate ("Parsol MCX", Givaudan) | 3.50 |
| 3-(4-Methylbenzylidene)camphor ("Eusolex 6300", Merck) | 3.0 |
| Esters of unsaturated fatty acids with glycerol and sorbitan ("Arlacel 481", ICI) | 6.00 |
| Microwax ("Lunacera 35", Fuller) | 1.00 |
| Caprylic/capric acid triglyceride ("Miglyol neutral oil", Dynamit-Nobel) | 2.0 |
| Myristyl alcohol, polyoxypropylated with 3 mol. of propylene oxide ("Witconol APM", Witco) | 119.0 |
| $C_{12}$-$C_{15}$ Alcohol benzoate ("Finsolv TN", Witco) | 30.0 |
| Magnesium stearate | 1.00 |
| Propylene glycol | 3.70 |
| Magnesium sulphate heptahydrate | 7.0 |
| Perfume, conservants, additives, stabilizers | as desired |
| Water, completely desalinated | to100.0 |

b. The total amount of antioxidant such as Vitamin C and derivatives (Column 9, lines 39-46) and the total amount of compounds that regulate energy metabolism such as D-Biotin and derivatives ( Column 10, lines 6-14) in the formulation as specified in the instant claims 2, 11 and 12.

c. Combination of antioxidant such as Vitamin C and derivatives and compounds that regulate metabolism such as D-Biotin and derivatives. Lazendorf teaches the preferable concentrations of antioxidant (1-10%) and preferable concentration of compounds such as biotin (0.1% to 10%) and states that the antioxidative active compounds can be combined with metabolic regulating compound at the stated concentrations. Additionally, Lazendorf provides an example of a composition comprising of D-biotin and Vitamin C dipalmitate at the ratio of 1:50 (% by weight)

(example 25, column 30, lines 21-51, see below). This reads on instant claims 14 and 15.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over to Sauermann et. al. (US 5710177).

Sauermann teaches a topical skin care composition comprising biotin and its esters, such as those described in the instant claims, in combination with alpha-hydroxycarboxylic acid and an antioxidant (abstract, claim 6, column 1, lines 62-column 5, Line 40). Among the biotin esters Sauermann teaches the compound identical to

formula I claimed in the instant claim 19 (Column 2, line 66 to Column 3 line 14. Among the antioxidants, Sauermann teaches vitamin C and its derivatives (column. 4, lines 53-56). Thus, choosing vitamin C as a suitable antioxidant in combination with the said biotin ester in a compositions would have been obvious for one of an ordinary skill in tha art at the time of the instant invention. Sauermann also suggests preparing topical compositions such as creams, lotions etc., by mixing the above components (examples) and hence reads on the claimed method.

Thus, the instant claims are *prima facie* obvious over the teachings of the prior art.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-22 of copending Application No. 10833983 (co-pending '983).

Claim 1 of instant application claims a method of making a composition for lightening the skin and/or smoothening skin color irregularities comprising admixing biotin, a biotin derivative or a salt thereof with a cosmetic additive or pharmaceutical additive. Claim 20 of co-pending '983 recites a method for preparing a composition for lightening the skin, smoothening skin color irregularities and/or treating senile lentignes comprising: combining a biotin compound selected from the group consisting of biotin salts, biotin derivatives, biotin derivative salts , and mixtures thereof with an additive. Claim 20 of co-pending '983. recites all the limitations of claim 1 of instant application and in addition recites an intended use of senile lentignes and use of mixtures of biotin and its derivatives in the composition.

Claim 2 in the instant application claims a method of making a composition for lightening the skin, smoothening skin color irregularities and/or treating senile lentigos comprising admixing biotin, a biotin derivative or a salt thereof with vitamin C or a vitamin C derivative. Claim 22 of co-pending '983 teaches all the limitations of claim 2 in the instant application and in addition recites the use of mixtures of vitamin C and Vitamin C derivatives in the composition.

Claim 3 in instant application recites a method of making composition claimed in claim 1 wherein the biotin derivative is a compound of formula I and formula II. Claim 21 in co-pending '983 recites all the limitations of the instant claim 3.

Although the conflicting claims (claims 1-3 in the instant application and claims 20- 22 in the co-pending application) are not identical as stated above, they are not patentably distinct from each other because the claims recite a method for preparing a composition by combining/mixing a biotin or biotin derivative with an additive which can be Vitamin C/ Vitamin C derivative.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

Claims 1-19 are rejected and no Claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 8 am to 5 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0567. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Savitha Rao
Examiner
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/Cecilia Tsang/
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